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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/682,837 | 10/23/2001 | David Stern | 3371.1 | 9174 |

22886 7590 09/17/2002

AFFYMETRIX, INC
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EXAMINER

FORMAN, BETTY J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1634

DATE MAILED: 09/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/682,837

Applicant(s)

STERN, DAVID

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 21-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II in Paper No. 6 is acknowledged. The traversal is on the grounds(s) that it would not be undue burden to examine the claims of all groups I and II. However, it is maintained that undue burden would be required to examine the claims of group I along with claims of group II as evidenced by the fact that the claims of groups I and II have acquired a separate status in the art as recognized by their different classifications as recognized by their divergent subject matter and because a search of the subject matter of invention I is not co-extensive with a search of inventions II.

Specifically, a search of the subject matter of invention I would include a search of nucleic acid analysis and analysis method steps, analysis reagents and reagent applications. In contrast a search of the subject matter of invention II would include a search of scanning systems, scanning components, and functionality of the scanning components. Therefore, a search of the subject matter of invention I is not co-extensive with a search of inventions II.

The requirement is still deemed proper and is therefore made FINAL.

Priority

2. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows: Provisional Applications 60/242,859 and 60/244,817 do not have a common inventor with the instant application. Therefore, Applicant's claim for priority to the above Provisional Applications is improper. Provisional

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Application 60/242,975 has a common inventor with the instant application. Applicant's claim for priority to the '975 Provision Application is proper.

119 (e)

(1) An application for patent filed under section 111(a) or section 363 of this title for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in a provisional application filed under section 111(b) of this title, **by an inventor or inventors named in the provisional application**, shall have the same effect, as to such invention, as though filed on the date of the provisional application filed under section 111(b) of this title, if the application for patent filed under section 111(a) or section 363 of this title is filed not later than 12 months after the date on which the provisional application was filed and if it contains or is amended to contain a specific reference to the provisional application.

Applicant is required to amend the first paragraph of the specification to correct Applicant's claim to priority.

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 2, 3, 5-12 and 16-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Rava et al (U.S. Patent No. 5,545,531, issued 13 August 1996).

Regarding Claim 2, Rava et al disclose scanning system for scanning a plurality of microarray disposed on a substrate comprising: a scanner apparatus constructed and arranged to detect emission signals from the substrate; a convertible processing apparatus (x-

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y-z table) including a containing member (i.e. holder) constructed and arranged to contain the substrate and a separating member (i.e. body containing channels which forms wells when placed on the substrate) which is constructed and arranged so that when the separating member is disposed in a first position (i.e. on the substrate) with respect to the containing members, at least two of the microarrays are fluidically separated from each other by the separating member and when the separating member is in a second position with respect to the containing members the at least two arrays are fluidically coupled with each other (Column 5, lines 16-65) wherein the substrate comprises a plurality of microarrays (Column 8, lines 1-5).

Regarding Claim 3, Rava et al disclose the scanner apparatus comprises an excitation radiation source; a focusing system constructed and arranged to focus radiation from the excitation source onto a selected first portion of the substrate; a radiation direction system constructed and arranged to scan the focused excitation radiation across the first portion of the substrate; a detector constructed and arranged to detect the emission signals from the first portion of the substrate in response to focused excitation radiation; and a data acquisition system constructed and arranged to record an amount of the emission signals detected as a function of the positions on the substrate (Column 6, line 34-Column 7, line 27).

Regarding Claim 5, Rava et al disclose the system wherein the radiation direction system includes a mirror selected from a galvanometric mirror and rotating polyhedral mirror (Column 6, lines 47-51).

Regarding Claim 6, Rava et al disclose the system wherein the focused excitation radiation is reciprocally scanned across a second portion of the substrate including at least two of the microarrays at a rate of at least 20 image lines per second i.e. each well comprising an array is read in less than 5 seconds (Column 6, lines 63-67).

Regarding Claim 7, Rava et al disclose the system wherein the data acquisition system includes a computer having a processor and a memory wherein the computer is constructed

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and arranged to receive image data representing the detected emission signals from the scanner apparatus and to store the image data in the memory (Column 6, lines 34-51 and Column 7, lines 4-12).

Regarding Claim 8, Rava et al disclose the system wherein the computer when executing a scanner control, data acquisition, and data analysis application is further constructed and arranged to control the focusing system and radiation direction system so as to sequentially focus on and irradiate a first of at least two microarrays and then sequentially focus on and irradiate one or more other microarrays (Column 5, lines 57-65).

Regarding Claim 9, Rava et al disclose the apparatus wherein the convertible processing apparatus is coupled to a translation stage; and the scanner apparatus further comprises a translation stage controller constructed and arranged to move the translation stage under the direction of the computer in coordination with the focusing system and radiation direction system (Column 5, lines 57-65).

Regarding Claim 10, Rava et al disclose the system wherein the translation stage controller moves the translation stage in an x direction and a y direction to sequentially position each of the microarrays for irradiation (Column 5, lines 25-29 and 57-65).

Regarding Claim 11, Rava et al disclose the system wherein x and y are orthogonal to each other (Column 5, lines 25-29 and 57-65).

Regarding Claim 12, Rava et al disclose the system wherein the translational stage controller moves the translation stage in a z direction orthogonal to a plane of the x and y so as to sequentially position each of the plurality of microarrays (Column 5, lines 25-29 and 57-65).

Regarding Claim 16, Rava et al disclose the system wherein the separating member includes one or more walls (i.e. channel walls) constructed and arranged to fluidically separate the at least two microarrays when the separating member is disposed in the first position (Column 8, lines 1-21).

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Regarding Claim 17, Rava et al disclose the system wherein the separating member includes a grid plate (i.e. the body comprises a grid-like arrangement of channels, see Fig. 4) wherein the grid plate includes a plurality of grid elements (i.e. channels) determined by the one or more walls wherein each of the microarrays is fluidically separated from each of the other microarrays by a grid element when the separating member is disposed in the first position (on the substrate) and wherein each of the microarrays is fluidically coupled with each other when the separating member is in the second position (i.e. off the substrate before and/or after placing the body on the substrate)(Column 8, lines 1-21 and Fig. 4).

Regarding Claim 18, Rava et al disclose the system wherein the plurality of grid elements is equal in number to the plurality of microarrays i.e. "the walls of the channels are placed on the wafer so that each surrounds and encloses the probe array" (Column 8, lines 9-11).

Regarding Claim 19, Rava et al disclose the system wherein the microarrays include synthesized probe arrays wherein the probe comprise oligonucleotides (Column 9, lines 10-27 and Column 10, lines 16-23).

Regarding Claim 20, Rava et al disclose the system wherein the plurality of microarrays are disposed on a contiguous surface of the substrate (Column 8, lines 1-21 and Fig. 4).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary

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skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rava et al (U.S. Patent No. 5,545,531, issued 13 August 1996) in view of Schembri et al (U.S. Patent No. 6,258,593 B1, filed 30 June 1999).

Regarding Claims 13-15, Rava et al disclose a scanning system for scanning a plurality of microarray disposed on a substrate comprising: a scanner apparatus constructed and arranged to detect emission signals from the substrate; a convertible processing apparatus including a containing member (i.e. disc cartridge with mini-clamps) constructed and arranged to contain the substrate and a separating member (i.e. body containing channels which forms wells when placed on the substrate) which is constructed and arranged so that when the separating member is disposed in a first position (i.e. on the substrate) with respect to the containing members, at least two of the microarrays are fluidically separated from each other by the separating member and when the separating member is in a second position with respect to the containing members the at least two arrays are fluidically coupled with each other (Column 5, lines 16-65) wherein the substrate comprises a plurality of microarrays (Column 8, lines 1-5) but they are silent regarding the structure of the holder. However, substrate holders comprising first and second segments were well known in the art at the time the claimed invention was made as taught by Schembri et al. Specifically, Schembri et al teach a similar substrate comprising substrate holders wherein the holders comprise first and second segments (i.e. housing and base) wherein the substrate is disposed between the segments (Claim 13); wherein the separating member is disposed between the first and second segments when the separating member is in the first position and is disposed apart from the first and second segments when the separating member is in the second position (Claim 14); and wherein the substrate is retained in place by the first and second segments (Claim 15)(Column 11, lines 9-52 and Fig. 1). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the substrate holder comprising

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first and second segments of Schembri et al to the substrate holder of Rava et al based on the teaching of Schembri et al wherein the first and second segments form a reusable reaction chamber with the substrate wherein mixing of reaction components is facilitated, reaction contamination is reduced and evaporation is prevented (Column 4, lines 26-37). Therefore, one skilled in the art would have been motivated to apply the reaction chamber of Schembri et al to the substrate holder of Rava et al for the obvious benefits of convenience and increased quality of reaction results as taught by Schembri et al (Column 4, lines 26-37).

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 2-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 5,981,956.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a scanning system comprising an apparatus for detecting emission signals from a substrate, containing members to contain the substrate, an excitation source, a focusing system, a data acquisition system, a computer and translation

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stage. Both sets of claims differ only in the instant claims recite scanning a plurality of microarrays and detecting emission from at least two of the plurality of microarrays. While the patent claims recite "substrate" (Claims 1-25) and do not recite a plurality of microarrays, the patent teaches a substrate encompasses a plurality of arrays on a surface (Column 15, lines 56-60). Therefore, the patent's claimed substrates encompass a surface having a plurality of arrays. As such, the instantly claimed substrate comprising a plurality of microarrays is obvious in view of the patent substrate teaching.

9. Claims 2-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,207,960 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a scanning system comprising an apparatus for detecting emission signals from a substrate, containing members to contain the substrate, an excitation source, a focusing system, a data acquisition system, a computer and translation stage. The sets of claims differ only in the instant claims recite scanning a plurality of microarrays and detecting emission from at least two of the plurality of microarrays. While the patent claims recite "substrate" (Claims 1-25) and do not recite a plurality of microarrays, the patent teaches a substrate encompasses a plurality of arrays on a surface (Column 15, lines 63-67). Therefore, the patent's claimed substrates encompass a surface having a plurality of arrays. As such, the instantly claimed substrate comprising a plurality of microarrays is obvious in view of the patent substrate teaching.

10. Claims 2-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,025,601 in view of Stern (U.S. Patent No. 5,981,956, issued 9 November 1999). Although the conflicting claims

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are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a scanning system comprising an apparatus for detecting emission signals from a substrate, containing members to contain the substrate, an excitation source, a focusing system, a data acquisition system, a computer and translation stage. The claim sets differ only in the instant claims recite scanning a plurality of microarrays and detecting emission from at least two of the plurality of microarrays. While the patent claims recite support having a sample (Claims 1-18) and do not recite a plurality of microarrays, a support having a sample wherein the sample comprises a plurality of microarrays was well known in the art at the time the claimed invention was made. Specifically, Stern teaches a similar scanning system comprising support having a plurality of microarrays and they teach the plurality of microarrays on a single support is a useful for scanning multiple arrays simultaneously (Column 15, lines 56-61). Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the support having multiple microarrays as taught in the '956 patent to the '601 support to thereby provide multiple microarrays on the support for the obvious benefits of scanning convenience as taught in the '956 patent (Column 15, lines 56-61).

Prior Art

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

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a. Kreek et al (U.S. Patent Application Publication No.2001/0053849 A1, filed 16 June 1999) teach a system for scanning a plurality of microarrays (§ 69-74).

b. Perov et al (U.S. Patent No. 6,407,395 B1, filed 29 February 2000) teach a system of scanning a plurality for microarrays (Column 3, lines 17-60).

c. Hang et al (U.S. Patent Application Publication No. 2002/0046712 A1, filed 1 March 2000) teach a system of scanning a plurality for microarrays (§ 57, 58 and 68).


Conclusion


12. Claim 4 is free of the prior art of record and may be placed in condition for allowance following resolution of the above rejections.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
September 9, 2002


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600